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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,591	01/24/2004	Doohi Lee	MMDL-1	7738

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EXAMINER	
CHAO, JUSTIN	
ART UNIT	PAPER NUMBER
3709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,591	LEE, DOOHI	
	Examiner	Art Unit	
	Justin Chao	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *papers through 1/24/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "the cross section" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 7 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Churchill 6,423,014 in view of Mourad 2002/0095087.

5. Regarding claim 1, Churchill discloses: the use of ultrasound (col 18, l. 35), verifying the treatment area by palpation (col 18, ll. 16-34), preparing the treatment area for treatment (col 18, ll. 34-38 where the “stretch and spray” technique can be a preparation for treatment), treating the pain through the prepared treatment area with

assistance from the ultrasound tool (col 18, ll. 34-38), and massaging the treatment area (col 18, ll. 34-38).

6. However, Churchill does not disclose the following limitation: obtaining at least one cross section of the body area using an ultrasound imaging tool, determining one or more clinically observable factors from the cross section related to the pain in the body area to determine a treatment area, verifying the treatment area while viewing the cross section through the ultrasound imaging tool.

7. Mourad teaches within the same field of endeavor: obtaining at least one cross section of the body area using an ultrasound imaging tool (para 8), determining one or more clinically observable factors from the cross section related to the pain in the body area to determine a treatment area (paras 59, 63), verifying the treatment area while viewing the cross section through the ultrasound imaging tool (paras 59, 63).

8. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Churchill in view of Mourad in order to "identify and spatially locate the exact source of ... pain" as taught by Mourad (para 57).

9. Regarding claim 7, Churchill in view of Mourad discloses the invention as claimed and as discussed above.

10. However, Churchill in view of Mourad does not positively recite massaging conducted under the guidance of the ultrasound imaging tool.

11. It would have been obvious to one of ordinary skill in the art at the time of the invention to massage the treatment area under the guidance of the ultrasound tool since the treatment area was determined via the ultrasound imaging tool to begin with.

12. Regarding claim 8, Churchill in view of Mourad discloses the invention as claimed and as discussed above.

13. However, Churchill in view of Mourad does not positively recite clinically observable factors including angle of pennation, bundle length of muscles, uniformity of relaxed and contracted muscles.

14. It is known that ultrasound imaging tools, such as the one taught by Mourad, are capable of discerning these clinically observable factors. As such, it would have been obvious to use such known observable factors to provide a more efficient and specific treatment.

15. Claims 2, 3, 6, 9, 10, 13-17, 19 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Churchill in view of Mourad further in view of Filly 6,379,307.

16. Regarding claim 2, Churchill in view of Mourad discloses the invention as claimed and as discussed above. Churchill further discloses: injecting anesthetic and medical drugs (col 18, ll. 34-38).

17. However, Churchill in view of Mourad does not disclose the following limitation: injecting under guidance of an ultrasound imaging tool.

18. Filly teaches within the same field of endeavor: injecting under guidance of an ultrasound imaging tool (col 1, ll. 46-60).

19. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Churchill in view of Mourad further in view of Filly in order for a "needle [to] be guided to a specific position within the body of the patient" as taught by Filly (col 1, ll. 60-62).

20. Regarding claims 3 and 10, Churchill in view of Mourad further in view of Filly discloses the invention as claimed and as discussed above. Churchill further discloses: stimulating muscles using a needle (col 18, ll. 34-38 disclosing "dry needling").

21. Regarding claims 6, 13 and 19, Churchill in view of Mourad further in view of Filly discloses the invention as claimed and as discussed above.

22. Filly further teaches: inserting an injection needle with a predetermined insertion angle as guided by a needle guide (16 fig 2; col 2, ll. 54-67).

23. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Churchill in view of Mourad further in view of Filly in order for "the needle [to] be guided to a specific position within the body of the patient" as taught by Filly (col 1, ll. 60-62).

24. Regarding claims 9, 16 and 20, Churchill in view of Mourad further in view of Filly discloses the invention as claimed and as discussed above.

25. Filly further teaches: marking a needle insertion point (figs 1-4 wherein insertion point is marked by slot 38).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Churchill in view of Mourad further in view of Filly in order for "the needle [to] be guided to a specific position within the body of the patient" as taught by Filly (col 1, ll. 60-62).

27. Regarding claim 14, Churchill in view of Mourad further in view of Filly discloses the invention as claimed and as discussed above.

28. However, Churchill in view of Mourad further in view of Filly does not positively recite massaging conducted under the guidance of the ultrasound imaging tool.

29. It would have been obvious to one of ordinary skill in the art at the time of the invention to massage the treatment area under the guidance of the ultrasound tool since the treatment area was determined via the ultrasound imaging tool to begin with.

30. Regarding claim 15, Churchill in view of Mourad further in view of Filly discloses the invention as claimed and as discussed above.

31. However, Churchill in view of Mourad further in view of Filly does not positively recite clinically observable factors including angle of pennation, bundle length of muscles, uniformity of relaxed and contracted muscles.

32. It is known that ultrasound imaging tools, such as the one taught by Mourad, are capable of discerning these clinically observable factors. As such, it would have been obvious to use such known observable factors to provide a more efficient and specific treatment.

33. Regarding claim 17, Churchill in view of Mourad further in view of Filly discloses the invention as claimed and as discussed above.

34. However, Churchill in view of Mourad further in view of Filly does not positively recite stimulating performed under a guidance of an ultrasound imaging tool.

35. It would have been obvious to one of ordinary skill in the art at the time of the invention to stimulate the treatment area under the guidance of the ultrasound tool since the treatment area was determined via the ultrasound imaging tool to begin with.

36. Claims 4, 5, 11, 12 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Churchill in view of Mourad further in view of Filly further in view of Masters 6,342,250.

37. Regarding claims 4, 11 and 18, Churchill in view of Mourad in view of Filly discloses the invention as claimed and as discussed above.

38. However, Churchill in view of Mourad further in view of Filly does not disclose the following limitation: using a combination of lidocaine and bupivacaine.

39. Masters teaches within the same field of endeavor: using a combination of lidocaine and bupivacaine (col 31, ll. 15-16).

40. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Churchill in view of Mourad further in view of Filly further in view of Masters to provide "management of acute and chronic pain" as taught by Masters (col 1, ll. 50-52).

41. Regarding claims 5 and 12, Churchill in view of Mourad in view of Filly further in view of Masters discloses the invention as claimed and as discussed above.

42. However, Churchill in view of Mourad in view of Filly further in view of Masters does not positively recite the following limitation: using a combination of about 40 percent 2% lidocaine and about 60 percent 0.25% bupivacaine.

43. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a combination of about 40 percent 2% lidocaine and about 60 percent 0.25% bupivacaine since it has been held that where the general conditions of a claim

are disclosed in the prior art, discovering the optimum or workable ranges involves only ordinary skill in the art. See MPEP 2144.05, *In re Aller,* 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Justin Chao whose telephone number is 571-270-3072. The examiner can normally be reached on Mon-Fri, alt Fri off, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on 571-272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justin Chao/
9/12/07

KIMBERLY S. SMITH
PRIMARY EXAMINER
9/12/07